37

potentiates an immune response to an animal, comprising an effective amount of said bioactive agent encapsulated in a biocompatible excipient to form microcapsules having a size between approximately 1 micrometer and approximately 10 micrometers, wherein said biocompatible excipient is a poly(lactide-co-glycolide), poly(lactide), poly(glycolide), copolyoxalate, polycaprolactone, poly(lactide-co-caprolactone), poly(esteramide), polyorthoester, poly( $\beta$ -hydroxybutyric acid), polyanhydride, or a mixture thereof.

- 33. The composition of claim 32, wherein said microcapsules have a size between approximately 5 micrometers and approximately 10 micrometers.
- 34. The composition of claim 32, wherein said microcapsules have a size between approximately 1 micrometer and approximately 5 micrometers.
- 35. The composition of claim 32, wherein said bioactive agent is a nutrient, immunomodulator, lymphokine, monokine, cytokine, or antigen.
- 36. The composition of claim 32, wherein said bioactive agent is an antigen.
- 37. The composition of claim 36, wherein said antigen is an allergen, viral antigen, bacterial antigen, protozoan antigen, or a fungal antigen.
- 38. The composition of claim 36, wherein said antigen is an influenzae antigen, Staphylococcus antigen, respiratory syncytial antigen, parainfluenza virus antigen, Hemophilus <sup>25</sup> influenza antigen, *Bordetella pertussis* antigen, *Neisseria gonorrhoea* antigen, *Streptococcus pneumoniae* antigen, *Plasmodium falciparum* antigen, helminthic pathogen antigen, or an antigen to vaccinate against allergies.
- 39. The composition of claim 36, wherein said antigen is 30 an influenza virus or staphylococcal enterotoxin B.
- 40. The composition of claim 36, wherein said bioactive agent further includes a cytokine.
- 41. The composition of claim 40, wherein said bioactive agent further includes an adjuvant.
- 42. The composition of claim 32, wherein said bioactive agent is a mixture of a cytokine and an adjuvant.
- 43. The composition of claim 32, wherein said bioactive agent comprises a peptide, protein, or nucleic acid.
- 44. The composition of claim 32, wherein the composition is for delivery to the mucosally associated lymphoreticular tissues of an animal, the mucosally associated lymphoreticular tissues are the Peyer's patch, the excipient is biodegradable, the microcapsules are capable of passing through the gastrointestinal tract without degradation, and the excipient is a poly(lactide-co-glycolide), poly 45 (glycolide), copolyoxalate, polycaprolactone, poly(lactide-co-caprolactone), poly(esteramide), polyorthoester, or a poly(β-hydroxybutyric acid).
- **45**. A composition for potentiating the immune response of an animal, comprising a mixture of effective amounts of first biocompatible microcapsules having a size less than approximately 10 micrometers and containing a bioactive agent encapsulated in a first biocompatible excipient and second biocompatible microcapsules containing a bioactive agent encapsulated in a second biocompatible excipient, said first microcapsules providing a primary immunological response and said second microcapsules releasing said agent contained in said second microcapsules in a pulsed manner to potentiate a subsequent immunological response.
- 46. A composition for delivering a bioactive agent to the mucosally associated lymphoreticular tissues of an animal, comprising an effective amount of said bioactive agent encapsulated in a biocompatible excipient to form microcapsules having a size between approximately 1 micrometer and approximately 10 micrometers, wherein said microcapsules comprise a mixture of a plurality of first microcapsules

having a size between approximately 1 micrometer and approximately 5 micrometers and a plurality of second microcapsules having a size between approximately 5 micrometers and approximately 10 micrometers for providing both a systemic immunity and a mucosal immunity to said animal.

- 47. A method of preparing a composition for delivering a bioactive agent that provides or potentiates an immune response to the mucosally associated lymphoreticular tissues of an animal, comprising the step of encapsulating effective amounts of said bioactive agent in a biocompatible excipient to form microcapsules having a size between approximately 1 micrometer and approximately 10 micrometers, wherein the excipient is a poly(lactide-co-glycolide), poly(lactide), poly(glycolide), copolyoxalate, polycaprolactone, poly (lactide-co-caprolactone), poly(esteramide), polyorthoester, poly( $\beta$ -hydroxybutyric acid), polyanhydride, or a mixture thereof.
- 48. The method of claim 47, wherein said microcapsules have a size between approximately 5 micrometers and approximately 10 micrometers so that said microcapsules can be retained in said mucosally associated lymphoreticular tissues.
- 49. The method of claim 47, wherein said microcapsules have a size between approximately 1 micrometer and approximately 5 micrometers so that said microcapsules can pass through said mucosally associated lymphoreticular tissues.
- **50**. The method of claim **47**, wherein said bioactive agent is a nutrient, immunomodulator, lymphokine, monokine, cytokine, or antigen.
- 51. The method of claim 47, wherein said bioactive agent comprises a peptide, protein or nucleic acid.
- 52. A method of preparing a composition for delivering a bioactive agent to the mucosally associated lymphoreticular tissues of an animal, comprising the step of encapsulating effective amounts of said bioactive agent in a biocompatible excipient to form microcapsules having a size between approximately 1 micrometer and approximately 10 micrometers, wherein said microcapsules are comprised of a plurality of first microcapsules having a size between approximately 1 micrometer and approximately 5 micrometers and a plurality of second microcapsules having a size between approximately 5 micrometers and approximately 10 micrometers, said first and second microcapsules can be administered to said animal to provide both a systemic immunity and a mucosal immunity.
- 53. A method of preparing a composition for providing systemic immunity in an animal, comprising the step of encapsulating effective amounts of a bioactive agent in a biocompatible excipient to form microcapsules having a size between approximately 1 micrometer and approximately 5 micrometers, wherein the excipient is a poly(lactide-coglycolide), poly(lactide), poly(glycolide), copolyoxalate, polycaprolactone, poly(lactide-co-caprolactone), poly (esteramide), polyorthoester, poly( $\beta$ -hydroxybutyric acid), polyanhydride, or a mixture thereof.
- 54. A method of preparing a composition for providing mucosal immunity in an animal, comprising the step of encapsulating effective amounts of a bioactive agent in a biocompatible excipient to form microcapsules having a size between approximately 5 micrometers and approximately 10 micrometers, wherein the excipient is a poly(lactide-coglycolide), poly(lactide), poly(glycolide), copolyoxalate, polycaprolactone, poly(lactide-co-caprolactone), poly (esteramide), polyorthoester, poly(β-hydroxybutyric acid), polyanhydride, or a mixture thereof.

\* \* \* \* \*